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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/026,032	10/25/2001	Marie Johannessen	5261.210-US	8734

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EXAMINER	
SCHNIZER, HOLLY G	
ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 09/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/026,032	JOHANNESSEN ET AL.	
	Examiner	Art Unit	
	Holly Schnizer	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 November 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *32-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 October 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. *09/148,440* .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *10-25-01* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of the Claims

The Preliminary Amendment filed 10-25-01 has been entered. Claims 1-31 have been cancelled and Claims 32-41 have been added. Claims 32-41 are pending and have been considered on the merits in this Office Action.

Specification

The Specification is objected to for inconsistencies between the Drawings and the Brief Description of the Drawings. The Brief Description of the Drawings on page 5, lines 14-18 refers to minipigs Nos. a-d in lines 15 and 18. However, Figures 1 and 2 are labeled as Animal Nos. 1, 2, 3, and 4. This inconsistency may be corrected by amending the Brief Description of the Drawings to refer to Animal Nos. or Minipig Nos. 1, 2, 3, and 4 rather than a, b, c, or d. Alternatively, the drawings may be amended to be consistent with the Brief Description.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 32-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 35 and 39 are indefinite because it is unclear as to whether they are properly dependent. Claims 35 and 39 depend from claims drawn to methods of treating a disease affectable by Factor VIIa or prolonging the half-life of Factor VIIa wherein the methods involve the use of modified factor VIIa. However, Claims 35 and 39 recite, "wherein the Factor VIIa is recombinant human Factor VIIa". The claims are confusing because they are unclear as to whether "the Factor VIIa" refers to the Factor VIIa that affects the disease to be treated or has a prolonged half-life, or to the modified FVIIa of the independent claims from which they depend. If "the Factor VIIa" refers to the Factor VIIa of line 1 of Claim 33, then Claim 33 is unclear as to how the method prolongs the half-life of recombinant human Factor VIIa by using a modified factor VIIa. If "the Factor VIIa" of Claims 35 and 39 are referring to the modified FVIIa, then the claims should be amended (for example, "wherein the modified FVIIa is a modified recombinant human factor VIIa". Clarification is required.

Claims 32 and 33 (and dependent Claims 34-41) are indefinite because the claims are unclear as to the metes and bounds of "substantially the same biological activity". The term "substantially" is a term of degree. Such a term of degree is allowable if the specification either defines the term or provides some standard for measuring the degree such that one of ordinary skill in the art would understand the metes and bounds of what is claimed. In the instant case, the Specification does not provide any such definition or standard for determining what activities are considered "substantially the same". Moreover, factor VIIa activities vary from assay to assay, from different purifications, or from different treatments. For example, the present

specification shows that the biological activity of the same factor VIIa is different when measuring after subcutaneous injection versus intravenous administration (see Table 3). Claims 34-41 are indefinite because they depend from Claims 32 and 33 yet do not correct the ambiguities therein.

Claims 32 and 33 (and dependent Claims 34-41) are indefinite as what is considered "authentic". "Authentic" means real or genuine. Therefore, does "authentic" refer to all factor VIIa proteins isolated from nature regardless of their sequences? Or, does "authentic include recombinant factor VIIa sequences and if so, which sequences are considered "authentic"? In the present claims, the "authentic" factor VIIa is used as a standard to measure activity levels. However, in order to determine when a particular modified factor VIIa has substantially the same activity for blood coagulation as "authentic" factor VIIa, knowledge the activity of the "authentic" factor VIIa or knowledge of its sequence is required. Therefore, in this regard, the claims are unclear because the identity of "authentic" factor VIIa is unclear. Clarification is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 32-41 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,310,183 in view of Nicolaisen et al. (U.S. Patent No. 5,580,560). Although the conflicting claims are not identical, they are not patentably distinct from each other.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims because the examined claim is either anticipated by, or would have been obvious over, the reference claim. See, e.g. In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

In the present case, the claims of U.S. Patent No. 6,310,183 (the '183 patent) and the instant application are all drawn to methods for treatment by subcutaneously administering an effective amount of factor VIIa or methods for prolonging the biological half-life of factor VIIa being administered by administering a composition comprising factor VIIa by subcutaneous injection. The claims of the '183 patent and the instant application differ in that the methods of the '183 patent claims are open to using any factor VIIa whereas the methods of the instant application claims are limited to using modified factor VIIa. However, the '183 patent defines factor VIIa as including authentic factor VIIa or modified factor VIIa provided that such factor VIIa has substantially the same biological activity for blood coagulation as authentic factor VIIa (see Col. 5, lines 11-15). Therefore, the claims of the '183 patent encompass using modified factor VIIa.

The benefits of using a modified factor VIIa in the method taught in the '183 patent would have been obvious to one of ordinary since modified factor VIIa molecules were available that had increased half, as evidenced by Nicolaisen et al. Therefore, it would have been obvious to one of ordinary skill in the art to use a modified factor VIIa, such as that disclosed in Nicolaisen et al., in the methods of treatment and prolonging the biological half life of factor VIIa taught in the '183 patent. One would have been motivated to use the modified factor VIIa of Nicolaisen et al. in the methods of the '183 patent to optimize the bioavailability of factor VIIa after administration into a patient; a common goal of both Nicolaisen et al. and the '183 patent.

Conclusions

No claims are allowable for the reasons described above.

A thorough search of the art did not reveal any teaching or suggestion that the subcutaneous administration of FVIIa, specifically, would result in prolonged half-life of the FVIIa as compared to the half-life of factor VIIa administered by other methods. Therefore, for this reason and for the reasons described in parent Application No. 09/148,440, it appears that the claims are free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Holly Schnizer whose telephone number is (703) 305-

3722. The examiner can normally be reached on Monday through Wednesday from 8 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703 308-0196.

Holly Schnizer
September 16, 2003

CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
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